

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

**IN RE: ETHICON, INC., PELVIC REPAIR  
SYSTEM PRODUCTS LIABILITY  
LITIGATION**

**Master File No. 2:12-MD-02327  
MDL 2327**

**JOSEPH R. GOODWIN  
U.S. DISTRICT JUDGE**

**REPLY IN SUPPORT OF MOTION TO EXCLUDE  
GENERAL-CAUSATION TESTIMONY OF NEERAJ KOHLI, M.D., M.B.A.**

While Dr. Kohli is well-credentialed, Ethicon requests that the Court exclude his opinions that are unreliable, irrelevant, unhelpful, or misleading under Federal Rules 702, 703, 402, and 403, and *Daubert*. Plaintiffs' contentions in opposition do not cure these fatal deficiencies. More specifically, Plaintiffs:

- are unable to controvert the cases throughout the country, including the Fourth Circuit, holding that evidence of alternative surgical techniques is irrelevant to design defect claims;
- cannot point to a reliable basis for his complication-rate opinion;
- concede that his clinical-studies-prediction opinion is inadmissible;
- fail to demonstrate a reliable basis for his opinion about TVT-O's appropriateness for certain patient populations;
- do not distinguish his opinions concerning the competency of other physicians from essentially identical opinions relying on the same record and arguments, which the Court has previously excluded as irrelevant;
- suggest that his opinions are based on personal experience when they are his ill-disguised narrative about Ethicon's knowledge, motive, and intent, based on his review of Ethicon's company documents, which are clearly prohibited under this Court's prior rulings;
- improperly argue that the Court should play the role of fact-finder with new evidence not relied on by Dr. Kohli in forming his opinions; and

- unjustifiably claim that the opinions are “widely known facts,” or “part of the general body of medical knowledge.”

Accordingly, as explained more fully below, Ethicon respectfully asks that the Court exclude the opinions of Dr. Kohli as set forth in its Memorandum. *See* Defs.’ Mem. (Dkt. 2809).

## **ARGUMENTS AND AUTHORITIES**

### **I. Dr. Kohli’s Design Defect Opinions Are Contrary to Uncontroverted Fourth Circuit Precedent Addressing the Same Arguments and Record.**

Dr. Kohli’s opinions conflating surgeons’ discretion and competency in prescribing and implanting TVT-O for a particular patient based on her medical history and conditions with alleged design defects for this medical device misunderstand and contort product liability law. All implantable medical devices necessarily require surgery for their use. But no physician was “required” to utilize an allegedly “difficult” transobturator surgical technique with TVT-O. *See* Pls.’ Opp’n (Dkt. 2178) at 4-6.<sup>1</sup> Nor is a surgeon’s competency or putative difficulty in implanting TVT-O relevant. *See* Defs.’ Mem. (Dkt. 2809) at 10 (discussing *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923 (S.D.W. Va. July 8, 2014). Rather, “[i]t is well established that a medical device manufacturer is not responsible for the practice of medicine.” *Sons v. Medtronic Inc.*, 915 F. Supp. 2d 776, 783 (W.D. La. 2013). “For physician-prescribed drugs and medical devices, the physician ‘is in the best position to understand the patient’s needs and assess the risks and benefits of a particular course of treatment.’” *Talley v. Danek Med., Inc.*, 179 F.3d 154, 163 (4th Cir. 1999).

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<sup>1</sup> Plaintiffs have incorporated and relied upon their arguments in their Wave 1 Memorandum in Opposition to Ethicon’s Motion to Exclude General-Causation Testimony of Neeraj Kohli, M.D., M.B.A. (Dkt. 2178). *See* Pls.’ [Wave 3] Opp’n (Dkt. 2944) at 1, incorporating documents in Dkt. 2178 in addition to supplemental arguments raised for the first time in their Wave 3 Memorandum in Opposition (Dkt. 2944). Accordingly, this Reply responds to both the original opposition arguments in Dkt. 2178, and the additional arguments raised by Plaintiffs in Dkt. 2944.

That a plaintiff's surgeon could have implanted the TVT-O mesh using a different surgical technique (*i.e.*, implanted TVT, using the retropubic technique), or chosen not to use any mesh at all, does not demonstrate a design defect in TVT-O. In *Talley*, the Fourth Circuit made clear that these assertions "questioned the medical judgment of doctors," and might be relevant in a malpractice suit against the doctor, but not a suit against the device manufacturer. *Id.* at 162. Surgical alternatives using the same device "[do] not indicate any design flaw." *Id.* Courts throughout the country have uniformly rejected Plaintiffs' proposition (*see* Defs.' Mem. (Dkt. 2809) at 3-5), and Plaintiffs cite no contrary case law that supports their erroneous legal argument (*see* Pls.' Opp'n (Dkt. 2178) at 4-5).

There is no conflict with this Court's prior rulings, as Plaintiffs argue. *See id.* at 5-6. This Court in *Tyree* addressed whether the expert's surgical-technique opinions were reliable, not whether they were relevant to support a design-defect claim. *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 560 (S.D.W. Va. 2014). Plaintiffs' reliance on *Huskey* is likewise inapposite because the Court again considered the *reliability* of Dr. Blaivas's opinions, not their relevancy. Ex. 1, Trial Tr. at 16:1-6, *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201 (S.D.W. Va. Aug. 28, 2014).

Ethicon has not argued here that testimony about alternative surgical techniques is irrelevant as to all claims. Rather, it asks the Court to rule consistent with the Fourth Circuit and courts around the country that, while alternative-surgical-technique opinions may support other claims, they do not support design-defect claims in general and cannot support that the TVT-O here in particular is defective in design. *See Talley*, 179 F.3d at 162; *see also* Defs.' Mem. (Dkt. 2809) at 2-5. Dr. Kohli's opinion about alternative-surgical-techniques is inadmissible if offered in support of plaintiffs' design-defect claim as it is irrelevant as a matter of law, and it should be

excluded under Rule 402.<sup>2</sup> See *Daubert*, 509 U.S. at 591-92 (explaining that an expert’s opinion must “fit” the relevant inquiry, and that scientific validity for one purpose is not necessarily scientific validity for other purposes).

## **II. Articles About Other Devices Do Not Support a Complication Rate Opinion for TVT-O, Especially a Purely Subjective Opinion.**

As to Plaintiffs’ original Opposition (Dkt. 2178), Ethicon responds as follows: Whether couched as one or two opinions, Dr. Kohli’s reliance solely on haphazard articles about other devices and surgical techniques does not suffice as proper methodology for a reliable TVT-O complication-rate opinion. See Defs.’ Mem. (Dkt. 2809) at 5-7. And Plaintiffs do not deny Ethicon’s contention that Dr. Kohli’s opinion is based on a blatant and unsystematic extrapolation of complications reported as to other devices. See Pls.’ Opp’n (Dkt. 2178) at 8-9. Plaintiffs simply claim that Rule 702 as interpreted by the Court permits this type of (flawed) methodology. *Id.* It does not.

In *Eghnayem*, the Court excluded Dr. Margolis’s complication-rate opinion because it was based on assumptions, not reliable methodology. *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 677 (S.D.W. Va. 2014). In *Tyree*, the Court excluded Dr. Margolis’s Xenform complication-rate opinion in part because he did not cite a single study involving Xenform slings. *Tyree*, 54 F. Supp. 3d at 523. And in *Huskey*, the Court excluded Dr. Blaivas’s complication-rate opinion because he did not explain his methodology. *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 721 (S.D.W. Va. 2014). Dr. Kohli’s complication-rate opinion suffers from

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<sup>2</sup> Plaintiffs’ argument that the cases disallowing surgical alternatives to support design defect claims were decided at summary judgment is a distinction without a difference. See Pls.’ Opp’n (Dkt. 2178) at 7. If the opinion is offered to support an improper basis for liability, it is irrelevant under Rule 402 and it violates the “relevance” or “fit” requirement under Rule 702 and *Daubert* and *Joiner*. See *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591-92 (1993); *Gen. Electric Co. v. Joiner*, 522 U.S. 136, 145-46 (1997).

all of these same flaws because he did not provide support from the TVT-O literature or his surgical experience, and he did not explain his methodology. Thus, this Court has routinely rejected—not endorsed—these types of flawed methodologies and their resultant unreliably based complication-rate opinions, and the Court should do so again here.

Plaintiffs misconstrue *Huskey* and *Winebarger*. The expert's failure to cite to specific TVT-O studies in *Huskey* was inconsequential because the opinion related to under-reporting of mesh complications generally, not solely for TVT-O. *Huskey*, 29 F. Supp. 3d at 720. Further, the expert relied upon several scientific studies that were directly on point. *Id.* Here, Dr. Kohli's opinion *does* relate specifically to TVT-O, and he does *not* cite to several on-point studies. In *Winebarger*, the expert was permitted to render safety and efficacy opinions based on his review of the literature and personal experience with the relevant products and procedures. *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at \*34 (S.D.W. Va. Apr. 24, 2015). The Court found that the lack of a direct-comparison study between the product and non-mesh procedures did not render the methodology unreliable. *Id.* Dr. Kohli not only lacks any direct-comparison study, but he also fails to provide relevant literature, surgical experience, or any other basis for his opinion. His opinion is wholly unsupported, and it should therefore be excluded. *See Gen. Electric Co.*, 522 U.S. at 145-46.

In their Wave 3 Opposition (Dkt. 2944), Plaintiffs supplement their position with the figurative argument that “Heraclitus,” “rivers,” and the “passage of time” have provided new information that supports Dr. Kohli's (unidentified) “opinions concerning complications.” *See* Pls.' Opp'n (Dkt. 2944) at 3-5. But Plaintiffs' new information and new arguments fail to demonstrate the reliability of Dr. Kohli's TVT-O complication rate opinion.

First, none of the articles and deposition testimony cited by Plaintiffs were relied upon by Dr. Kohli. *See* Ex. B to Defs.’ Mot. (Dkt. 2806-2), Kohli Report at 41-44. Thus, Plaintiffs have effectively asked the Court to assess the reliability of their *counsel’s* use of the information—not Dr. Kohli’s.

Second, Plaintiffs improperly ask the Court to evaluate “additional” information as a fact-finder and agree with their out-of-context interpretations that conclude that this information is “reflective of main stream understanding.” *See* Pls.’ Opp’n (Dkt. 2944) at 4. The relevant inquiry, however, is the reliability of *Dr. Kohli’s* opinion based on the data and information *he* relied upon. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) (“The inquiry to be undertaken by the district court . . . focus[es] on the ‘principles and methodology’ employed by the expert.”) (emphasis added); *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1384 (4th Cir. 1995) (noting that *Daubert* requires “the methodology employed by the expert” to be sound). Plaintiffs’ new arguments simply amount to “after-the-fact rationalizations of expert testimony” previously criticized by the Court when it first excluded the testimony of Dr. Kohli, and should therefore be disregarded. *See Gen. Electric Co.*, 522 U.S. at 145-46; *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582233, at \*2-3 (S.D.W. Va. Sept. 1, 2016).

Last, Plaintiffs now offer to correct Dr. Kohli’s subjective complication rate opinion by having him mislead the jury into believing that midurethral slings (again—not TVT-O, but all slings that utilize its insertion technique) have “double . . . the complication rate” of retropubic slings. *See* Pls.’ Opp’n (Dkt. 2944) at 5. Plaintiffs’ apparent plan is to have Dr. Kohli point out figures cited in a recently published article that mentions how one study found transobturator

tapes to have a 9.7% rate of neuromuscular pain compared to 4.5%<sup>3</sup> for all retropubic tapes. *Id.* But this “double the complication rate” opinion fails for the same reasons discussed above and more—namely, (1) new opinions are not permitted by this Court; (2) Dr. Kohli did not rely on the article cited by Plaintiffs; and (3) Plaintiffs do not in any way demonstrate how the rates provided in this one article—which reports on rates published in a different article, about specific complications, involving numerous different products—demonstrate a reliable overall complication rate that holds true for TVT-O in all patients, for all time, under all circumstances. Ethicon respectfully requests that the Court not allow Plaintiffs to use Dr. Kohli as a conduit for opinions not provided in his report and not based on reliable information and data.

At bottom, Dr. Kohli’s TVT-O complication-rate opinion remains subjective, over-general, and unsupported; it amounts to nothing more than his *ipse dixit* or his personal belief, and—as the Court ruled in its Wave 1 Order—should be excluded again.

### **III. Plaintiffs Do Not Contest the Unreliability of Dr. Kohli’s Clinical-Studies-Prediction Opinion.**

The Court should grant Ethicon’s request to exclude Dr. Kohli’s clinical studies predictions opinion based on Plaintiffs’ representation that no such opinion will be offered at trial. *See* Pls.’ Opp’n (Dkt. 2178) at 9, (Dkt. 2944) at 5.

### **IV. Dr. Kohli’s Opinion Concerning TVT-O’s Appropriateness for Certain Patient Populations Remains Unsupported and Unhelpful.**

As to Plaintiffs’ original opposition arguments (Dkt. 2178), Plaintiffs inexplicably cite to a portion of Dr. Kohli’s expert report addressing his surgeon-training opinions to suggest that he supported his opinions two pages later concerning TVT-O’s appropriateness for certain patient populations. *Compare* Pls.’ Opp’n (Dkt. 2178) at 10 (citing Kohli Report at 33), *with* Defs.’

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<sup>3</sup> This figure is incorrect. The article cited by Plaintiffs identifies a 5.4% rate. *See* Ex. D to Pls.’ Opp’n (Dkt. 2944-4) at 4.

Mem. (Dkt. 2809) at 9 (citing opinions in Kohli Report at 35). Yet the surgeon-training opinions expressed by Dr. Kohli have nothing to do with the marketing opinions challenged here, nor does the surgeon-training portion of his report offer support for this challenged marketing opinion.

Even if, as Plaintiffs claim, Dr. Kohli relied upon internal company documents, the opinion would still be unhelpful based on the Court's ruling in *Edwards* and thus inadmissible under Rule 702. In *Edwards*, the Court determined that the jurors were capable of interpreting company documents for themselves and required no expert interpretation. *Edwards*, 2014 WL 3361923, at \*10. Thus, Dr. Rosenzweig's opinion, which was essentially identical to Dr. Kohli's opinion here, was unhelpful and inadmissible. *Id.* Dr. Kohli's "one-size-fits-all" marketing opinion<sup>4</sup> should therefore be excluded as well.

In their supplemental opposition (Dkt. 2944), Plaintiffs incorrectly claim that Dr. Kohli relied upon information cited in footnotes 40 and 41 in his expert report to support his opinion about TVT-O's appropriateness for certain patient populations. *See* Pls.' Opp'n (Dkt. 2944) at 5. He did not. Footnote 40 was offered by Dr. Kohli to support a different opinion alleging "sales rep propaganda."<sup>5</sup> *See* Ex. B to Defs.' Mot. (Dkt. 2806-2), Kohli Report at 35. Footnote 41 was offered by Dr. Kohli to support his opinion regarding alleged difficulty of the surgical technique. *Id.* The Court has already considered Dr. Kohli's "appropriateness for certain patient populations" opinion and found it was "unaccompanied by any support." *In re: Ethicon Inc.*,

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<sup>4</sup> Plaintiffs' discussion of Dr. Kohli's trocar-trajectory opinion is inapposite because Ethicon does not challenge that opinion as unreliable for lack of support, or for improper citation to company documents. Rather, Dr. Kohli's trocar opinion should be excluded because: (1) it constitutes an improper alternative-surgical-technique opinion if offered to prove a design defect and is thus irrelevant, and (2) it is irrelevant as an opinion concerning physician competency. *See* Defs.' Mem. (Dkt. 2809) at 2-5, 10.

<sup>5</sup> This opinion is yet another example of Dr. Kohli's improper narrative review of company documents. *See* Defs.' Mem. (Dkt. 2809) at 10-12.



2016 WL 4582233, at \*3. This basic deficiency has not changed. Plaintiffs' entirely unsupported, vague assertion that Dr. Kohli's opinion is based on "generalized facts that are consistent with the medical community at large," Pls.' Opp'n (Dkt. 2944) at 5, further reveals that the Court was correct in finding Dr. Kohli's opinion to be *ipse dixit*. *In re: Ethicon Inc.*, 2016 WL 4582233, at \*3. Accordingly, this opinion should again be excluded.

**V. Dr. Kohli's Surgeon-Competence Opinions are Irrelevant and Misleading Regardless of the Purpose for Which They are Offered.**

The Court has already ruled that Dr. Kohli's opinions addressing the competence of other surgeons in implanting TVT-O, including the effect of the trocar design on surgeon technique, are irrelevant and unhelpful. *In re: Ethicon Inc.*, 2016 WL 4582233, at \*3; *Edwards*, 2014 WL 3361923, at \*17. Contrary to Plaintiffs' incorrect assertion that these are mere design-defect opinions, Dr. Kohli's report is replete with references to surgeons allegedly experiencing difficulty with implanting TVT-O just like the opinions excluded in *Edwards*. See Defs.' Mem. (Dkt. 2809) at 10 (citing Kohli Report at 9, 25, 32). And surgical technique difficulties nonetheless do not constitute design defects for the reasons discussed above. See also *Bogle v. Sofamor Danek Grp., Inc.*, No. 95-8646, 1999 WL 1132313, at \*4 (S.D. Fla. Apr. 9, 1999) (finding claim that device should have been designed to be less difficult to implant did not identify a defect in the product, but rather that it was a product reserved to a top-rate surgeon).

Plaintiffs' argument provides no basis for the Court to depart from its earlier ruling, that Dr. Kohli's surgeon-competency opinions are excluded. See *In re: Ethicon Inc.*, 2016 WL 4582233, at \*3; *Mathison v. Boston Scientific Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at \*23 (S.D.W. Va. May 6, 2015) (adhering to the Court's earlier ruling where the expert's rejected opinions were unchanged from those already addressed). Nor do Plaintiffs offer any argument in

opposition to Ethicon’s contention that Dr. Kohli’s physician-competency opinions fail under Rule 403.

Rather, Plaintiffs now offer the supplemental argument that the Court should admit Dr. Kohli’s surgeon-competency opinions based on their bald assertion that the opinions are “part and parcel of the general body of medical knowledge.” Pls.’ Opp’n (Dkt. 2944) at 6. Despite the lack of support for this assertion, it does not address the basis for the Court’s exclusion of these opinions—their irrelevancy. *In re: Ethicon Inc.*, 2016 WL 4582233, at \*3.

Accordingly, Dr. Kohli’s surgeon-competency opinions should be excluded.

**VI. Plaintiffs Disregard the Court’s Firm Rulings That Statements Concerning Knowledge, Motive, Intent, and a Narrative Review of Documents are Inadmissible.**

Although Plaintiffs claim that Dr. Kohli will not offer opinions about Ethicon’s intent, motives, or state of mind, they suggest that Dr. Kohli’s opinions are nonetheless admissible because they are “based largely on his clinical observations or his personal experience.” Pls.’ Opp’n (Dkt. 2178) at 12. Dr. Kohli’s opinions intrude precisely in the manners expressly prohibited by the Court. *See* Defs.’ Mem. (Dkt. 2809) at 11-12. If these “opinions” were based on Dr. Kohli’s clinical observations and personal experience, he would not need to refer extensively to company documents, and particularly those that make no mention of him.

Further, in the limited times Dr. Kohli addresses his personal involvement, he offers subjective feelings about the events. *See, e.g., id.* (referring to Dr. Kohli’s self-described “sense” and “feelings” about Ethicon and TVT-O history). Such subjective beliefs are not valid expert opinions, and they should be excluded accordingly. *Daubert*, 509 U.S. at 590; *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 151-52 (1999). After reviewing the identical opposition arguments from Plaintiffs that they again offer here, the Court again ruled that state-of-mind opinions and parroting of corporate documents are prohibited. *In re: Ethicon Inc.*, 2016 WL 4582233, at \*4.

Because Plaintiffs *still* do not concede to the Court's ruling in this regard, Ethicon respectfully requests that the Court again exclude such testimony offered by Dr. Kohli.

### CONCLUSION

Ethicon asks this Court to grant its Motion to Exclude the General Causation Testimony of Neeraj Kohli, M.D., M.B.A., and limit his opinions for the reasons stated above and in its memorandum in support of its motion.

Respectfully submitted,

ETHICON, INC. AND  
JOHNSON & JOHNSON

/s/ Rita A. Maimbourg

Rita A. Maimbourg  
TUCKER ELLIS LLP  
950 Main Avenue, Suite 1100  
Cleveland, OH 44113-7213  
Telephone: 216.592.5000  
Facsimile: 216.592.5002  
[rita.maimbourg@tuckerellis.com](mailto:rita.maimbourg@tuckerellis.com)

/s/ David B. Thomas

David B. Thomas (W.Va. Bar #3731)  
THOMAS COMBS & SPANN PLLC  
300 Summers St.  
Suite 1380 (25301)  
P.O. Box 3824  
Charleston, WV 25338  
Telephone: 304.414.1807  
[dthomas@tcspllc.com](mailto:dthomas@tcspllc.com)

/s/ Christy D. Jones

Christy D. Jones  
BUTLER SNOW LLP  
1020 Highland Colony Parkway  
Suite 1400 (39157)  
P.O. Box 6010  
Ridgeland, MS 39158-6010  
Telephone: 601.985.4523  
[christy.jones@butlersnow.com](mailto:christy.jones@butlersnow.com)

**CERTIFICATE OF SERVICE**

I certify that on October 20, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Rita A. Maimbourg

Rita A. Maimbourg

TUCKER ELLIS LLP

950 Main Avenue, Suite 1100

Cleveland, OH 44113-7213

Telephone: 216.592.5000

Facsimile: 216.592.5002

[rita.maimbourg@tuckerellis.com](mailto:rita.maimbourg@tuckerellis.com)